

### **REMARKS/ARGUMENTS**

Claims 1 - 37 remain pending in the application. Claims 1 – 37 stand rejected and claim 31 is objected to. Through this amendment, twenty-four claims (claims 1-3, 5-7, 9-18, 21, 23, 30-31, and 34-37) are amended. No new matter has been introduced into the application. As explained in more detail below, the Applicants submit that all claims are now in condition for allowance and respectfully request such action.

#### **Rejection under 35 U.S.C. §101**

Claims 1 – 12 and 13 – 37 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. Specifically, the Office Action asserts the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory. Regarding claims 1 and 13, the Examiner suggests replacing “implanted” with “implantable” in order to overcome the 101 rejections. In view of the Examiner’s recommendation, the Applicants have amended claims 1-3, 5-6, 9-14, 17-18, 21, and 23 to recite an implantable component, and therefore respectfully request withdrawal of this rejection.

#### **Rejection under 35 U.S.C. §102**

Claims 1 – 14, 22 – 31 and 35 – 36 are rejected under 35 USC §102(b) as being anticipated by Schulman et al (US 6,208,894). The Applicants have amended independent claims 1, 2, 3, 7, 9, 10, 11, 12, 13, 14, 15, 16, 23, 30, 34, 35, and 36 to replace “feature” with

“mode of operation” in order to clarify what is being claimed. The amendments are supported by the specification as originally filed, e.g., Paragraphs 179- 185.

The Office Action cites the Schulman reference as disclosing a medical device system having several internal devices, an external device, and external patient unit. The Examiner further cites the reference as having many features, such as for example, communication between the transceiver and clinician’s programmer or between the patient control unit and the clinician’s programmer. The features, as taught by Schulman, appear to merely identify typological details of the medical device system and not the mode of operation.

The present invention, however, relates to an implantable component being capable of multiple modes of operation in a multi-modal operation. To more clearly define this aspect of the present invention, claims 1, 11, 13 and 37 have been amended to indicate an implantable device is “configured for multi-modal operation” and claims 1-3, 7, 9-16, 23, 30, and 34-37 have been amended to more clearly indicate the features of the implantable device are modes of operation. In view of the Applicant’s amendment and the absence of an implantable device capable of multi-modal operation being taught or otherwise disclosed in the Schulman reference, Applicants request reconsideration of claims 1 – 14, 22 – 31 and 35 – 36 and withdrawal of the rejection.

### **Rejections under 35 U.S.C. §103**

Claims 15 and 37 are rejected under 35 USC §103(a) as being unpatentable over Schulman, et al. (US 6,208,894). The Office Action alleges that Schulman suggests the elements of claims 15 and 37. The Office Action alleges (Page 6, item 1. Emphasis added.):

Schulman et al. teaches the device substantially as claimed, but fails to teach the first feature corresponds to an open-loop treatment therapy and the second feature corresponds to a closed-loop treatment therapy. However, Schulman et al. does not disclose that the clinician's programmer 172, through the second feature, is capable of programming the SCU 302 operation. This includes programming the SCU 302 to operate in with an open or closed loop capacity. As long as it was initially programmed to operate in this capacity, then it **will continue** even if the connection degrades.

Schulman merely teaches continuing supporting whatever feature was operating before connection degrades. For example, if Schulman's device were programmed to operate with closed-loop therapy, the device will continue to operate in the closed-loop therapy after the connection degrades. However, Schulman does not even suggest the claim element "if the external component and the implantable component are decoupled, continuing to operate the medical device system with the open-loop mode of the treatment therapy" as included in claim 37. Moreover, even if Schulman does disclose a clinician's programmer that is capable of programming the SCU operation, the Schulman still does not disclose or otherwise suggest an implantable device being configured for multi-modal operation as presented in claims 13 (from which claim 15 depends) and 37. The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection.

Claims 16 – 19 and 32 – 33 are rejected under 35 USC §103(a) as being unpatentable over Schulman, et al. (US 6,208,894) in view of Fabian, et al. (US 6,735,479). Claims 16-19 and 32-33 ultimately depend from claim 13. Moreover, Fabian does not make up for the deficiencies of Schulman. Thus, claims 16-19 and 32-33 are patentable for at least the above reasons. The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection.

Claims 20 and 34 are rejected under 35 USC §103(a) as being unpatentable over Schulman, et al. (US 6,208,894) in view of Massicotte, et al. (US Patent Publication

20040068195). Claims 20 and 24 ultimately depend from claim 13. Moreover, Massicotte does not make for the deficiencies of Schulman. Thus, claims 20 and 34 are patentable for at least the above reasons. The Applicants request reconsideration of claims 20 and 34.

Claims 21-22 are rejected under 35 USC §103(a) as being unpatentable over Schulman, et al. (US 6,208,894) in view of Kaib (US 6,169,387). Claims 21 and 22 ultimately depend from claim 13. Moreover, Massicotte does not make for the deficiencies of Schulman. Thus, claims 21-22 are patentable for at least the above reasons. The Applicants request reconsideration of claims 21-22. Moreover, the Office Action alleges that Kaib discloses an alarming system configured to activate upon the disconnecting of an implanted component. An aspect of the present invention, however, is directed to an implantable device capable of different modes of operation depending on connections with external components. For example, as disclosed in the application, the medical device system supports a first mode of operation and a second mode of operation that are associated with the treatment therapy. The medical device system may support both when the implantable component and the external component are coupled, thus exchanging data. If the external component is decoupled, the implantable component continues to support the first feature. (See Page 3, paragraph 7). In view of the fact that neither Kaib nor Schulman disclose or suggest the claimed invention, the Applicants respectfully request reconsideration and withdrawal of the rejection.

### **Claim Objections**

Claim 31 is objected to because of informalities. More specifically, the Examiner recommends changing the second “(e)” to “(f)”. In view of the Examiner’s recommendation, the second “(e)” of claim 31 has been changed to “(f)”.

**CONCLUSION**

All rejections having been addressed, Applicants respectfully submit that the instant application is in condition for allowance, and respectfully solicit prompt notification of the same. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the number set forth below.

Respectfully submitted,

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